January 17, 2024

The Honorable Charles E. Schumer
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, D.C. 20510

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
Washington, D.C. 20510

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
Washington, D.C. 20510

Dear Speaker Johnson, Leader Jeffries, Leader Schumer, and Leader McConnell,

We are writing to urge your bipartisan leadership and engagement on national security and emerging biotechnology challenges facing Americans through the prompt reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA). As the PAHPA reauthorization legislative language is finalized, we urge you to support the inclusion of provisions strengthening the Federal Select Agent Program (FSAP) included in S. 2333.

For more than two decades, the FSAP has been a cornerstone of federal oversight of laboratory research on potentially dangerous pathogens. Bipartisan support for the program has allowed for iterative improvements to program authorities, ensuring that it can provide effective oversight over both public and private U.S. laboratories that work with biological select agents and toxins. We support the following language in the text reported to the Senate on September 6, 2023:

- **Section 402**. This section would authorize creation of an anonymous and voluntary FSAP no-fault reporting system, addressing a key outstanding recommendation that would help generate applied biosafety data to develop evidence-based standards for biosafety and biocontainment. This system would also aid researchers in complying with FSAP by providing an avenue to obtain program guidance and feedback. The interagency Federal Experts Security Advisory Panel (FESAP) in 2014 identified gaps in FSAP's control of select agents in 2014 and proposed regulatory modifications needed to ensure biosafety and biosecurity. Based on the FESAP report, the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) created an implementation plan in 2015 for those regulatory modifications. As of 2022, the FSAP program has yet to address all of the recommendations laid out in both the FESAP and FTAC-SAR reports, including those addressing no-fault reporting of laboratory incidents.
- **Section 403**. To ensure consistency across the various federal biosafety and biosecurity policies and frameworks, this section charges the National Science Advisory Board for Biosecurity and external stakeholders to integrate FSAP and other federal biosecurity guidance and produce recommendations to mitigate biological risks from existing federal oversight gaps. We hope this evaluation will also clarify the roles, responsibilities, and authorities both within and between relevant agencies and recommend necessary restructuring.

We also support the following provision but recommend that the text be modified to remove ambiguity and ensure consistent interpretation and compliance of FSAP terms. And require input from external technical experts given the rapid evolution of biotechnology:

- **Section 401**. Current advances in biotechnology have allowed for the creation of synthetic, chimeric, and modified select agents, which can be used for legitimate research and pharmaceutical development but also for malicious purposes. Modified language for this section would adapt FSAP to better fit the new biological threat landscape by including input from industry and academic stakeholders to establish methods and metrics for determining select agent thresholds, identify responsibilities, verify compliance, and create mechanisms for timely clarification.

Together these provisions establish a pathway to regulate synthetic, chimeric, and modified select agents, and create an anonymous and voluntary no-fault reporting system. They comprehensively modernize FSAP ensuring emerging biosecurity and biosafety risks are mitigated and allowing researchers to interface with the program to strengthen compliance.

As the promise of new innovation is realized across the biotechnology field, Congress must ensure the development of FSAP biosafety and biosecurity best practices to maintain the benefits of select agent research while reducing the risks. We look forward to working closely with your offices to strengthen oversight of select agents and offer our endorsement of Congress passing comprehensive FSAP reform.

Sincerely,

Milana Boukhman Trounce, MD
Clinical Professor and Director BioSecurity Program, Stanford University

Anita Cicero, JD
Deputy Director, Johns Hopkins University Center for Health Security

Kevin M. Esvelt, PhD
Massachusetts Institute of Technology

David Gillum, MS
University of Nevada, Reno
2020 President, American Biological Safety Association International

Tom Inglesby, MD
Director, Johns Hopkins University Center for Health Security

Gregory Koblentz, PhD
Director, Biodefense Graduate Program
George Mason University

Joshua Morrison, JD
President, 1Day Sooner

Gerald W Parker, DVM, PhD
Former Deputy Assistant Secretary of Defense for Chemical and Biological Defense Programs

Margaret Rush, PhD
Chief Scientific Officer and Partner, Gryphon Scientific

Alec Stapp
Co-Founder, Institute for Progress

Hon. Andrew C. Weber, MSFS
Former Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs